K062746

NOV 20 2006

510(k) Executive Summary

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter
Name, address,
Contact

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Date Prepared: July 12, 2006

Device Name

Proprietary name: Medicon Ferritin – LATEX

Common name: Ferritin Reagent

Classification name: Ferritin Immunological Test

Device Description

The Ferritin – LATEX is an immunoturbidimetric assay. When serum or plasma specimen is mixed with the appropriate buffer (R1) and latex particles coated with anti-ferritin antibodies (R2), ferritin reacts with the antibodies leading to agglutination of latex particles. This agglutination is detected as turbidity change (600 nm) and it is proportional to ferritin concentration in the sample.

Reagent Composition:

Reagent	Components
R1	120 mM Tris buffer pH=8.2 Accelerator Surfactant Stabilizers Preservatives
R2	Latex particles coated with rabbit anti-human ferritin in 20 mM Tris buffer pH=8.4 Stabilizers Preservatives

510(k) Summary, Continued

Kit Format:

Cat No.	Quantity	Storage
1418-0270	4x6 ml R1+4x1.25ml R2	2-8°C
1418-0279	4x24ml R1+4 x 5ml R2	

Intended use

In vitro diagnostic reagent intended for the determination of Ferritin in human serum and plasma using Olympus AU 400/600/640 automated clinical chemistry analyzers.

Indications For Use

Medicon Ferritin –LATEX reagent is for the determination of Ferritin in human serum and plasma using automated clinical chemistry analyzers.

The measurement of ferritin may aid in the diagnosis of diseases affecting iron metabolism.

Substantial Equivalance

The Ferritin – LATEX is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Olympus Ferritin Reagent (K030124). Both products are intended for use in the quantitative determination of Ferritin on Olympus AU 400/600/640 automated clinical chemistry analyzers.

Substantial equivalence-Similarities

The following table compares the Medicon Ferritin – LATEX with the predicate device.

Feature	Ferritin - LATEX	Ferritin (predicate)
Intended Use	*In vitro* diagnostic reagent intended for the determination of Ferritin in human serum and plasma using Olympus AU 400/600/640 automated clinical chemistry analyzers.	*In vitro* diagnostic reagent intended for the determination of Ferritin in human serum using automated Olympus clinical chemistry analyzers.

Indication for Use	Medicon Ferritin –LATEX reagent is for the determination o Ferritin in human serum and plasma using automated clinical chemistry analyzers. The measurement of ferritin may aid in the diagnosis of diseases affecting iron metabolism.	Reagent for the determination of ferritin concentrations in human serum using Olympus family of clinical chemistry analyzers. Serum ferritin is an indicator of body iron stores: it has been shown to correlate with stainable bone marrow iron. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.
Assay Protocol	Particle enhanced Immunoturbidometric	Particle enhanced Immunoturbidometric
Instrument	Olympus Clinical Chemistry Analyzers	Olympus Clinical Chemistry Analyzers
Formulation	Final reactive ingredients: Tris Buffer pH: 8.2 Latex particles coated with rabbit anti-human ferritin Preservative	Final reactive ingredients: Tris Buffer pH: 8.2 Latex particles coated with rabbit anti-human ferritin Preservative
Calibrator	Olympus Serum Protein Multi-Calibrator ODR3021	Olympus Serum Protein Multi-Calibrator ODR3021
Controls	Olympus ITA Control Sera, ODC0014, ODC 0015, ODC 0016	Olympus ITA Control Sera, ODC0014, ODC 0015, ODC 0016

Substantial equivalence-Similarities

The following table compares the Ferritin – LATEX with the predicate device.

Feature	Ferritin - LATEX	Ferritin (predicate)
Reagent Stability	On board: 30 days	On board: 30 days
Calibration Interval	After each lot and 14 days	After each lot and 14 days
Traceability/ Standardization	Standardized against the 3rd International Standard for ferritin, Recombinant NBSC code:94/572.	Standardized against the 3rd International Standard for ferritin, Recombinant NBSC code:94/572

Substantial equivalence-differences

The following table compares the Ferritin – LATEX with the predicate device.

Feature	Ferritin - LATEX	Ferritin (predicate)
Measuring Range	4 –450 ng/ml	8 –450 µg/l
Sample type	Serum and plasma	Serum
Reference Intervals	Serum / Plasma: Infants – 1 month: 6-400 ng/ml 1 month – 6 months: 6-410 ng/ml 6 months – 12 months: 6–80 ng/ml 1 year – 5 years: 6–60 ng/ml 6 years – 19 years: 6–320 ng/ml adult men: 20-250 ng/ml adult women: 20-200 ng/ml	Serum: New born infants – 6 months: 25- 200µg/l 6 months – 15 years: 7-142 µg/l Adult male: 20-300µg/l Adult female: 10-120µg/l

Substantial equivalence-Performance Characteristics

The performance characteristics of the Ferritin-LATEX and the predicate device are compared in the table below:

Feature	Ferritin - LATEX	Ferritin (predicate)
Precision	**Within run CV** 3.20% @ 38.0 ng/ml 1.31% @ 108.1 ng/ml 0.99% @ 224.1 ng/ml **Total CV** 3.94% @ 38.0 ng/ml 1.62% @ 108.1 ng/ml 1.43% @ 224.1 ng/ml	**Within run CV** 2.25% @ 40.0 ng/ml 2.00% @ 101 ng/ml 1.25% @ 383 ng/ml **Total CV** 3.43% @ 40.0 ng/ml 2.81% @ 101 ng/ml 2.12% @ 383 ng/ml
Analytical sensitivity (LDL)	4ng/ml	6.4 µg/L
Linearity	4 – 450 ng/ml	8.0 – 450 µg/L

Method Comparison	Linear regression analysis: Ferritin-LATEX v.s. commercially available ferritin assay on patient serum samples y= 1,0016x+4,3849 R= 0.9958 Ferritin-LATEX between patient serum and EDTA plasma y= 0,9847x – 1.1275 R= 0.9987 Ferritin-LATEX between patient serum and Li-Heparine plasma y= 0,9778x + 1.2886 R= 0.9988	Linear regression analysis: Predicate device v.s. commercially available ferritin assay on patient serum samples y= 0,964x-2,549 R= 0.995
Interferences	• Haemolysis: Less than 5% up to 500 mg/dl hemoglobin. • Lipemic: Less than 10% up to 400mg/lL Intralipid®. • Icterus: Less than 5% up to 20mg/dl bilirubin. • Rheumatoid Factor: Less than 5% up to 900 IU/ml RF. • Ascorbic acid: Less than 5% up to 3 mg/dl ascorbic acid.	• Haemolysis: Less than 10% up to 5 g/L hemoglobin. • Lipemic: Less than 10% up to 400mg/dL Intralipid®. • Icterus: Less than 5% up to 40mg/dL or 684 µmol/l bilirubin. • Rheumatoid Factor: Less than 5% up to 500 IU/ml RF.
Prozone Effect	No hook effect observed up to 10000 ng/ml.	No hook effect observed up to 5000 ng/ml.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mecicon Hellas S.A.
c/o Mr. Daniel W. Lehtonen
2307 East Aurora Road
Twinsburg, OH 44087

NOV 20 2006

Re: k062746
Trade/Device Name: Medicon Ferritin-LATEX
Regulation Number: 21 CFR 866.5340
Regulation Name: Ferritin Immunological Test System
Regulatory Class: Class II
Product Code: DBF
Dated: September 13, 2006
Received: September 14, 2006

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

maria m Chan for
Dr Robert Becker

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K062746

Device Name: Medicon Ferritin - LATEX

Indications for Use:

Medicon Ferritin –LATEX reagent is for the determination of Ferritin in human serum and plasma using automated clinical chemistry analyzers.

The measurement of ferritin may aid in the diagnosis of diseases affecting iron metabolism.

For *in vitro* diagnostic use.

Prescription Use --√----- (Part 21 CFR 801 Subpart D) AND/OR Over- The Counter –Use -------- (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic **Device** Evaluation and Safety

510(k) K062746